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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 801

[Docket No. 99N–4955]

Amendment of Various Device Regulations to Reflect Current American Society for Testing and Materials Citations; Confirmation in Part and Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule; confirmation in part and technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is confirming, in part, the direct final rule amending certain references in various medical device regulations. The amendments update the references in those regulations to various standards of the American Society for Testing and Materials (ASTM) to reflect the current standards designations. In addition, FDA is correcting errors made in the direct final rule regarding ASTM's address and an FDA zip code.

DATES: The direct final rule published on January 24, 2000 (65 FR 3627), as amended by this rule, is effective June 7, 2000.

FOR FURTHER INFORMATION CONTACT: Philip L. Chao, Office of Policy, Planning, and Legislation (HF–23), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3380.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of January 24, 2000 (65 FR 3627), FDA published a direct final rule and a companion proposed rule to amend various medical device regulations. The amendments would update references in those regulations to various standards issued by the American Society for Testing and Materials (ASTM). The preamble to the direct final rule and the companion proposed rule explained that ASTM had been working on a project

to help Federal agencies update and maintain the ASTM standards that are referenced in the Code of Federal Regulations. As part of the ASTM project, ASTM informed FDA that many ASTM standards cited in FDA's food additive and device regulations were out-of-date and provided a list of standards with their current year designations.

Based on information received from ASTM, FDA, through the direct final rule and companion proposed rule, identified several device regulations that contained obsolete or withdrawn ASTM standards. The medical device regulations and the ASTM standards at issue are:

• 21 CFR 801.410 *Use of impact-resistant lenses in eyeglasses and sunglasses*—The agency proposed to amend paragraph (d)(2) by replacing ''ASTM Method D 1415–68 'Test for International Hardness of Vulcanized Rubber,''' with ''ASTM Method D 1415–88, 'Standard Test Method for Rubber Property—International Hardness,''' and also replace ''ASTM Method D 412–68 'Tension Test of Vulcanized Rubber''' with ''ASTM Method D 412–97, 'Standard Test Methods for Vulcanized Rubber and Thermoplastic Rubbers and Thermoplastic Elastomers—Tension'''.

• 21 CFR 801.430 *User labeling for menstrual tampons*—The agency sought to amend paragraph (f)(2) by replacing ''(ASTM), D 3492–83, 'Standard Specification for Rubber Contraceptives (Condoms)''' with ''(ASTM) D 3492–96, 'Standard Specification for Rubber Contraceptives (Male Condoms)'''.

FDA received one comment. The comment, submitted by ASTM, pointed out that because ASTM had revised two of the cited ASTM references again, the two references in the direct final rule were now obsolete. ASTM recommended changing D412–97 to D412–98A and D3492–96 to D3492–97 to reflect the current ASTM cites. ASTM's comment explained how the standards had changed and provided detailed descriptions of the changes in its comment. In general, the changes were not significant; some changes involved removing terms that were not commonly used or defined, deleting redundant wording, adding metric measurements, and changing measurement methods to improve accuracy or clarity.

Because these changes are not significant and ASTM has already made these changes to its standards, FDA finds for good cause that notice and public comment on the latest ASTM standards citation revisions is unnecessary.

Therefore, FDA is confirming, in part, the direct final rule insofar as it pertains to § 801.410 and its reference to ASTM Method D 1415–88, ''Standard Test Method for Rubber Property—International Hardness'' and the addresses where the standards may be found or inspected. Similarly, FDA is confirming the addresses in § 801.430 where the standards may be found or inspected, although it is correcting errors that were made in the direct final rule regarding the ASTM's address.

FDA is amending § 801.410 by replacing ''ASTM Method D 412–97'' with ''ASTM Method D 412–98A'' and using the current title for ASTM method D 412.98A. FDA is also amending § 801.430(f)(2) by replacing ''(ASTM), D 3492–96,'' with ''(ASTM) D 3492–97,''.

List of Subjects 21 CFR Part 801

Hearing aids, Medical devices, Professional and patient labeling.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner of Food and Drugs, the direct final rule published on January 24, 2000 (65 FR 3627), is confirmed as effective June 7, 2000, with the following changes:

PART 801—LABELING

1. The authority citation for part 801 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 360i, 360j, 371, 374.

§ 801.410 [Amended]

2. Section 801.410 ''*Use of impact-resistant lenses in eyeglasses and sunglasses*'' is amended in paragraph (d)(2) by removing ''ASTM Method D 412–97, Standard Test Methods for Vulcanized Rubber and Thermoplastic Rubbers and Thermoplastic Elastomers—Tension,'' and by adding in

its place ''ASTM Method D 412–98A, 'Standard Test Methods for Vulcanized Rubber and Thermoplastic Elastomers—Tension','' and by removing ''10850'' and by adding in its place ''20850''.

§ 801.430 [Amended]

3. Section 801.430 ''*User labeling for menstrual tampons*'' is amended in paragraph (f)(2) by removing ''(ASTM), D 3492–96, 'Standard Specification for Rubber Contraceptives (Condoms)''' and by adding in its place ''(ASTM) D 3492–97, 'Standard Specification for Rubber Contraceptives (Male Condoms)'''; and by revising the footnote to read ''Copies of the standard are available from the American Society for Testing and Materials, 100 Barr Harbor Dr., West

Conshohocken, PA 19428, or available for inspection at the Center for Devices and Radiological Health's Library, 9200 Corporate Blvd., Rockville, MD 20850, or at the Office of the **Federal Register**, 800 North Capitol St., NW., suite 700, Washington, DC.''

Dated: 6/28/00
June 28, 2000

Margaret M. Dotzel,
Associate Commissioner for Policy.

[FR Doc. 00–???? Filed ??–??–00; 8:45 am]

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